DEC 2 9 2004

K042713

# 510(k) SUMMARY

## SUBMITTED BY

Tom Brewer
Spine Next America
8381 Dix Ellis Trail
Suite 110
Jacksonville, Fl. 32256

Date Submitted: September 27, 2004

## CLASSIFICATION, COMMON OR USUAL NAME, DEVICE NAME

Classification Name: Vertebral Body Replacement Device
Common/Usual Name: Vertebral Body Replacement
Product Classification: Class II
Proprietary Name: Spine Next FIDJI Vertebral Body Replacement Type 5

## PREDICATE DEVICE

Vertebral Spacer manufactured by Synthes [reference 510(k) K011037, cleared July 1, 2002]

Vertestack manufactured by Medtronic Sofamor Danek [reference 510(k) K031780, cleared July 30, 2003]

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR §807.92.

## DEVICE DESCRIPTION AND MATERIALS OF CONSTRUCTION

The Spine Next FIDJI Vetebral Body Replacement Type 5 devices are hollow blocks that are machined from extruded Polyetheretherketone (PEEK); the blocks are tapered to aid in maintaining lordosis of the spine following implantation. The devices have angled teeth on the cephalad and caudal surfaces. The devices include tantalum inserts that serve as a location and orientation markers for radiographs.

## INDICATIONS FOR USE

The FIDJI vertebral body replacement type 5 device is intended for use in the thoracolumbar spine (T1-L5) to replace a collapsed, damaged, or unstable vertebral body

due to tumor or trauma (i.e., fracture). The vertebral body replacement can be used with Spine Next supplemental internal fixation systems, e.g., the SHIRAZ and SHIRAZ JAVA systems. The interior of the device can be packed with bone.

## COMPARISON TO THE PREDICATE DEVICE

| **PRODUCT** | **FIDJI** | **Vertebral spacer/Vertestack** |
|---|---|---|
| Materials of Construction | PEEK Optima LT | PEEK Optima LT |
| Load Bearing | Yes | Yes |
| Sold sterile | Yes | Yes |
| Biocompatible | Yes | Yes |
| Same Indications | Yes | Yes |
| Similar Use/Handling | Yes | Yes |
| Provided in various sizes | Yes | Yes |

Comparison of Technical Characteristics with the Predicate Device

- ✓ Both the Spine Next Vertebral Body Replacement type 5 and the predicate devices are used as Spinal vertebral body replacements.
- ✓ Technologically they are virtually identical in their function and principle of operation, although subtle design differences will require minor adjustments to procedure by the implanting surgeon for proper product use. Both devices are similar in that they are intended for use under load conditions.
- ✓ Both the Spine Next Vertebral Body Replacement type 5 and the predicated devices are fabricated from PEEK Optima LT
- ✓ All devices meet mechanical performance requirements.
- ✓ All devices have similar indications-for-use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 2 9 2004

Ms. Lisa Peterson
Regulatory Affairs Manager
Spinal Concepts, Inc.
5301 Riata Park Court, Building. F
Austin, Texas 78727

Re: K042713
Trade/Device Name: FIDJI Vertebral Body Replacement Type 5
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: II
Product Code: MQP
Dated: December 3, 2004
Received: December 6, 2004

Dear Ms. Peterson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

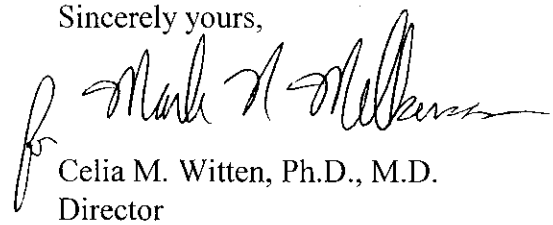
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative, and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K042713

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K042713

Device Name:

Spinal Concepts, Inc. **FIDJI Vertebral Body Replacement Type 5**

Indications for Use:

FIDJI type 5 is a vertebral body replacement device that is intended for use in the thoracic and/or thoracolumbar spine (T1-L5) to replace a collapsed, damaged or unstable vertebral body resected or excised (i.e., partial or total vertebrectomy procedures) due to tumor or trauma (i.e., fracture). The device is designed to restore the biomechanical integrity of the anterior, middle, and posterior spinal column even in the absence of fusion for a prolonged period. This device is intended to be used with bone graft and supplemental fixation, such as the Spinal Concepts, Inc. InCompass System. Additionally, FIDJI type 5 is intended to be used in a paired configuration.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark A Milhem

**(Division Sign-Off)**
**Division of General, Restorative, and Neurological Devices**

**510(k) Number** K042713